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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,646	02/10/2004	Neil E. Forsberg	6954-007	1833
20575	7590	12/14/2006	EXAMINER	
MARGER JOHNSON & MCCOLLOM, P.C. 210 SW MORRISON STREET, SUITE 400 PORTLAND, OR 97204			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/776,646

Applicant(s)

FORSBERG ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/12/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Homology Results</u> .        |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's provisional election with traverse of Group III, claims 27-36 and SEQ ID Numbers 11 and 12, during a telephone conversation with Ms. Kaplan on September 11, 2006 is acknowledged.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 28 and 34 also withdrawn from further consideration as being drawn to non-elected invention (non-elected SEQ ID Numbers).

### ***Information Disclosure Statement***

The IDS received on October 12, 2004 is acknowledged.

A signed copy of the PTO-1449 is enclosed herein.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the sequences depicted in Figure 1 are not legible. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Applicants are also advised that the sequences disclosed in Figure 1 must comply with Sequence Rules set forth in 37 CFR 1.821(a)-(h). Any sequence disclosure of nucleotide sequences

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comprising more than 10 consecutive nucleotides must be accompanied by a proper SEQ ID Number. For the disclosed sequences which are required to be compliant, a CRF, fully compliant with the above stated rules, a substitute paper Sequence Listing, and a statement as required in 37 CFR 1.821(f).

A fully compliant response must fulfill this requirement.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 29-33, 35, and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Iwen et al. (U.S. Patent No. 6,872,523 B1, issued March 29, 2005, filed May 30, 2000) in view of Cohen et al. (U.S. Patent No. 5,939,265, issued August 17, 1999).

Iwen et al. disclose a nucleic acid sequences derived from *Aspergillus fumigatus* (herein, *A. fumigatus*), wherein said nucleic acid comprises ITS (internal transcribed spacer) regions, which is explicitly known and disclosed as being located between 18S and 28S rRNA genes, and “offer distinct advantages over molecular targets including sensitivity due to the existence of 100 copies per genome.” (column 2, lines 10-15).

In particular, Iwen et al. disclose a nucleic acid depicted by SEQ ID Number 35, which comprises 100% homology over SEQ ID Numbers 11 and 12 of the instant application (see enclosed Sequence Homology Results).

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Iwen et al. disclose and contemplate a kit comprising the necessary reagents for the detection of said nucleic acid sequence from *A. fumigatus*.

Iwen et al. do not explicitly disclose the primers depicted by SEQ ID Numbers 11 and 12.

Iwen et al. do not explicitly disclose that their kit should comprise a container, instructions, or a preservative.

Cohen et al. disclose a well known practice of making a kit comprising necessary reagents for testing/diagnostics, wherein the artisans contemplate the packaging of a preservative so as to maintain the integrity of the collected sample specimens (column 37, lines 27-32).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Iwen et al. with the teachings of Cohen et al., thereby arriving at the claimed invention for the following reasons.

The basis of the instant rejection does not give any patentable weight to the intended use of conferred by the phrase, "for detecting or measuring fungal contaminations in a sample," or the phrase, "for diagnosing jejunal hemorrhage syndrome," because the claims are drawn to a kit, that is, a product. As a product is strictly defined by the elements of said product, so long as the prior art anticipates or renders the elements of the product obvious over the prior art, the claims are properly rejected.

The kit, as claimed by the instant application, comprises a pair of primers which are capable of detecting the presence of *A. fumigatus*. Whether the detection is "for" the diagnosis of a condition such as JHS, or "for" the detection of the presence of the pathogen in no way confers any patentable weight.

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As discussed earlier, Iwen et al. already discloses a nucleic acid sequence derived from *A. fumigatus*, wherein said nucleic acid comprises a sequence which is 100% homologous over all bases of primers depicted by SEQ ID Numbers 11 and 12 of the instant application.

Since the target nucleic acid is known, it is respectfully submitted that derivation of any primer sequences which can amplify/detect said target nucleic acid is not inventive and would have been fully well within the purview of an ordinarily skilled artisan at the time the invention was made.

With regard to the limitations imposed by claims 29 and 30, such limitations do not confer any patentable weight since the limitation further limits the sample types for the intended use, which has not been given patentable weight.

In other words, whether the primers of Iwen et al. is used "for" the detection of *A. fumigatus* in a biological sample or fee or food sample in no way changes the physical attribute of the primers. Since the claims are drawn to a product, whether said product is intended to detect the presence of the pathogen in food, fecal, or biological sample is irrelevant and does not alter the structure of the product, failing to distinguish the product over the prior art.

In addition, one of ordinary skill in the art at the time the invention was made would have been motivated to package the contents disclosed by Cohen et al., that is, preservatives, into the kit of Iwen et al. for the well known advantage of preserving the integrity of the collected sample.

Finally, with regard to the instructions comprised in said kit, such does not confer any patentable weight because an instruction is a non-functional descriptive material only reciting the intended use of the kit.

Such finding is consistent with the precedents set by the court.

In *In re Haller* (C.C.P.A. 73 USPQ 403, April 1997), the court expressed that in order for the article or composition of matter (*i.e.*, product) be patentable, such must not only be useful and

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involve invention, but it also must be *new*. The court stated that if the product has no novelty, a patent cannot be granted on it *regardless of its intended use* (at 404). The court, citing *In re Thomas J. Dixon*, 18 C.C.P.A. 711, 44 F.2d 881, 7 USPQ 209; *In re Robert C. Russell*, 18 C.C.P.A. 1184, 48 F.2d 668, 9 USPQ 181; *In re Reeves*, 20 C.C.P.A. 767, 62 F.2d 199, 16 USPQ 110; *In re McKee*, 20 C.C.P.A. 1018, 64 F.2d 379, 17 USPQ 293; and *In re Hansen*, 33 C.C.P.A. 979, 154 F.2d 684, 69 USPQ 332, expressed that, “[I]t is well settled that the application of particular printed matter to an old article cannot render the article patentable.” (at 405), concluding that the mere labeling of an old composition as an insecticide does not make it a new of different composition within the meaning of the patent statutes, the situation of which is analogous as that of *In re Thuau*, which attempted to patent an old product on the basis of a statement that it is intended for a new use. The court continued to express that such statement of intended use appearing in the claim or in a label on the product was *immaterial* so far as the question of patentability was concerned (at 405).

Therefore, in view of the above court decision, the instant kit claim(s) comprising old products cannot be “*new*” based on its intended use printed on the recited instruction material as such intended use is “*immaterial*” as far as the question of patentability is concerned.

Similarly, in *In re Ngai*, 70 USPQ 2d 1862 (CAFC 2004) the court, referencing *In re Gulak*, 703 F.2d 1381 (Fed. Cir. 1983), held that addition of a new set of instructions into a known kit does *not* interrelate with the kit in the same way as the numbers interrelate with the kit in the same way as the numbers interrelated with the band (as in *Gulak*). The court held that the printed matter in no way depends on the kit, and the kit does not depend on the printed matter expressing that if a patent were to be granted solely on the presence of a different printed instructions, “anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product,”

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concluding that a known product by simply attaching a set of instructions to that product would not be entitled a new patent.

Therefore, for the foregoing reasons, the claims are deemed *prima facie* obvious over the cited references.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

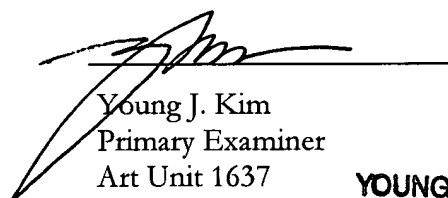
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by

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applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Primary Examiner  
Art Unit 1637  
11/22/2006

**YOUNG J. KIM  
PRIMARY EXAMINER**

YJK

# *Sequence Alignment*

SEQ ID NO: 11

US-09-580-797-35

; Sequence 35, Application US/09580797

; Patent No. 6872523

; GENERAL INFORMATION:

; APPLICANT: Iwen, Peter C.

; APPLICANT: Hinrichs, Steven H.

; APPLICANT: Henry, Travis

; APPLICANT: Board of Regents of the University of Nebraska

; TITLE OF INVENTION: Materials and Methods for Molecular

; TITLE OF INVENTION: Detection of Clinically Relevant Pathogenic Fungal Species

; FILE REFERENCE: UNMC 63149

; CURRENT APPLICATION NUMBER: US/09/580,797

; CURRENT FILING DATE: 2000-05-30

; NUMBER OF SEQ ID NOS: 39

; SOFTWARE: FastSEQ for windows Version 3.0

; SEQ ID NO 35

; LENGTH: 597

; TYPE: DNA

; ORGANISM: Aspergillus fumigatus

US-09-580-797-35

Query Match 100.0%; Score 21; DB 3; Length 597;

Best Local Similarity 100.0%; Pred. No. 0.23;

Matches 21; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 AACCTCCACCCGTGTCTATC 21

Db 54 AACCTCCACCCGTGTCTATC 74

SEQ ID NO: 12

RESULT 2

US-09-580-797-35/c

; Sequence 35, Application US/09580797

; Patent No. 6872523

; GENERAL INFORMATION:

; APPLICANT: Iwen, Peter C.

; APPLICANT: Hinrichs, Steven H.

; APPLICANT: Henry, Travis

; APPLICANT: Board of Regents of the University of Nebraska

; TITLE OF INVENTION: Materials and Methods for Molecular

; TITLE OF INVENTION: Detection of Clinically Relevant Pathogenic Fungal Species

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; NUMBER OF SEQ ID NOS: 39

; SOFTWARE: FastSEQ for windows Version 3.0

; SEQ ID NO 35

; LENGTH: 597

; TYPE: DNA

; ORGANISM: Aspergillus fumigatus

US-09-580-797-35

Query Match 100.0%; Score 15; DB 3; Length 597;

Best Local Similarity 100.0%; Pred. No. 79;

Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GCGGCCGTCGAAACG 15

Db 115 GCGGCCGTCGAAACG 101